



PATENT  
Docket No.: 19603/2615 (CRF D-2408)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Barany et al. ) Examiner: R. Hutson  
Serial No. : 09/830,502 )  
Cnfrm. No. : 8225 ) Art Unit: 1652  
Filed : October 29, 1999 )  
For : HIGH FIDELITY THERMOSTABLE LIGASE )  
AND USES THEREOF )

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§ 1.97-1.98

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05/06/2004 MGEBREM1 00000067 09830502  
02 FC:1806 180.00 0P

Respectfully submitted,

Date: May 4, 2004



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Institute for form 1449A/PTO				<i>Complete if Known</i>	
				Application Number	09/830,502
				Filing Date	October 29, 1999
				First Named Inventor	Barany et al.
				Art Unit	1652
				Examiner Name	R. Hutson
Sheet	1	of	7	Attorney Docket Number	19603/2615 (CRF D-2408)

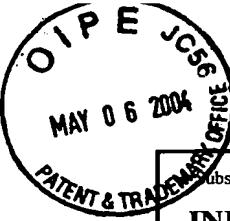
U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number - Kind Code <sup>2</sup> (if known)			
1	US-4,683,202	07/28/1987	Mullis		
2	US-4,883,750	11/28/1989	Whiteley et al.		
3	US-5,470,705	11/28/1985	Grossman et al.		
4	US-6,576,453	06/10/2003	Barany et al.		
5	US-6,054,564	04/25/2000	Barany et al.		
6	US-5,494,810	02/27/1996	Barany et al.		
7	US-5,496,699	03/05/1996	Sorenson		
8	US-5,506,137	04/09/1996	Mathur et al.		
9	US-5,516,663	05/14/1996	Backman et al.		
10	US-5,728,526	03/17/1998	George, Jr. et al.		
11	US-5,912,148	06/15/1999	Eggerding		
12	US-6,312,892	11/06/2001	Barany et al.		
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FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
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13	WO 91/17239			11/14/1991	WIPO
14	WO 98/03673			01/29/1998	WIPO
15	WO 00/26381			05/11/2000	WIPO
16	WO 97/31256			08/28/1997	WIPO
17	WO 97/45559			12/04/1997	WIPO
18	WO 93/17126			09/02/1993	WIPO

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Substitute for form 1449B/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	09/830,502
Sheet	2	of	7	Filing Date	October 29, 1999
				First Named Inventor	Barany et al.
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				Examiner Name	R. Hutson
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	19	Kreiner, T., "Rapid Genetic Sequence Analysis Using a DNA Probe Array System," <i>American Laboratory</i> 39-43 (March 1996)		
	20	Kovach et al., "Mutation Detection by Highly Sensitive Methods Indicates That p53 Gene Mutations in Breast Cancer Can Have Important Prognostic Value," <i>Proc. Natl Acad. Sci. USA</i> 93:1093-96 (1996)		
	21	Lin et al., "Multiplex Genotype Determination at a Large Number of Gene Loci," <i>Proc. Natl. Acad. Sci. USA</i> 93:2582-87 (1996)		
	22	Tavormina et al., "Thanatophoric Dysplasia (Types I and II) Caused by Distinct Mutations in Fibroblast Growth Factor Receptor 3," <i>Nature Genetics</i> 9:321-328 (1995)		
	23	Barany et al., "Cloning, Overexpression and Nucleotide Sequence of a Thermostable DNA Ligase-Encoding Gene," <i>Gene</i> 109:1-11 (1991)		
	24	Sidransky et al., "Identification of <i>ras</i> Oncogene Mutations in the Stool of Patients With Curable Colorectal Tumors," <i>Science</i> 256:102-105 (1992)		
	25	Brennan et al., "Molecular Assessment of Histopathological Staging in Squamous-Cell Carcinoma of the Head and Neck," <i>The New England Journal of Medicine</i> 332(7):429-35 (1995)		
	26	Berthélémy et al., "Identification of K- <i>ras</i> Mutations in Pancreatic Juice in the Early Diagnosis of Pancreatic Cancer," <i>Annals of Internal Medicine</i> 123(3):188-91 (1995)		
	27	Hayashi et al., "Genetic Diagnosis Identifies Occult Lymph Node Metastases Undetectable by the Histopathological Method," <i>Cancer Research</i> 54:3853-56 (1994)		
	28	Tada et al., "Detection of <i>ras</i> Gene Mutations in Pancreatic Juice and Peripheral Blood of Patients with Pancreatic Adenocarcinoma," <i>Cancer Research</i> 53:2472-74 (1993)		

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	29	Tada et al., "Clinical Application of <i>ras</i> Gene Mutation for Diagnosis of Pancreatic Adenocarcinoma," <i>Gastroenterology</i> 100:233-38 (1991)			
	30	Mitsudomi et al., "Mutations of <i>ras</i> Genes Distinguish a Subset of Non-Small-Cell Lung Cancer Cell Lines From Small-Cell Lung Cancer Cell Lines," <i>Oncogene</i> 6:1353-62 (1991)			
	31	Day et al., "Detection of Steroid 21-Hydroxylase Alleles Using Gene-Specific PCR and a Multiplexed Ligation Detection Reaction," <i>Genomics</i> 29:152-62 (1995)			
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	33	Abravaya et al., "Detection of Point Mutations With a Modified Ligase Chain Reaction (Gap-LCR)," <i>Nucleic Acids Research</i> 23(4):675-82 (1995)			
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	35	Jen et al., "Molecular Determinants of Dysplasia in Colorectal Lesions," <i>Cancer Research</i> 54:5523-26 (1994)			
	36	Redston et al., "Common Occurrence of APC and K- <i>ras</i> Gene Mutations in the Spectrum of Colitis-Associated Neoplasias," <i>Gastroenterology</i> 108:383-92 (1995)			
	37	Lu et al., "Quantitative Aspects of the Mutant Analysis by PCR and Restriction Enzyme Cleavage (MAPREC)," <i>PCR Methods and Applications</i> 3:176-80 (1993)			
	38	Kuppuswamy et al., "Single Nucleotide Primer Extension to Detect Genetic Diseases: Experimental Application to Hemophilia B (factor IX) and Cystic Fibrosis Genes," <i>Proc. Natl. Acad. Sci. USA</i> 88:1143-47 (1991)			

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PTO/SB/08B (10-01)

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	4	of	7	Attorney Docket Number	19603/2615 (CRF D-2408)
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
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	39	Rust et al., "Mutagenically Separated PCR (MS-PCR): A Highly Specific One Step Procedure for Easy Mutation Detection," <i>Nucleic Acid Research</i> 21(16):3623-29 (1993)		
	40	Suzuki et al., "Detection of <i>ras</i> Gene Mutations in Human Lung Cancers by Single-Strand Conformation Polymorphism Analysis of Polymerase Chain Reaction Products," <i>Oncogene</i> 5:1037-43 (1990)		
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	42	Reynolds et al., "Analysis of Genetic Markers in Forensic DNA Samples Using the Polymerase Chain Reaction," <i>Anal. Chem.</i> 63:2-15 (1991))		
	43	Buyse et al., "Rapid DNA Typing of Class II HLA Antigens Using the Polymerase Chain Reaction and Reverse Dot Blot Hybridization," <i>Tissue Antigens</i> 41:1-14 (1993)		
	44	Gyllensten et al., "PCR-Based HLA Class II Typing," <i>PCR Meth. Appl.</i> 1:91-98 (1991)		
	45	Chamberlain et al., "Deletion Screening of the Duchenne Muscular Dystrophy Locus Via Multiplex DNA Amplification," <i>Nucleic Acids Res.</i> 16:11141-56 (1988)		
	46	Tsui, L. C., "Mutations and Sequence Variations Detected in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Gene: A Report From the Cystic Fibrosis Genetic Analysis Consortium," <i>Human Mutat.</i> 1:197-203 (1992)		
	47	Hollstein et al., "p53 Mutations in Human Cancers," <i>Science</i> 253:49-53 (1991)		
	48	Saiki et al., "Enzymatic Amplification of $\beta$ -Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," <i>Science</i> 230:1350-1354 (1985)		

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	49	Wu et al., "The Ligation Amplification Reaction (LAR) -- Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," <i>Genomics</i> 4:560-69 (1989)		
	50	Landegren et al., "A Ligase-Mediated Gene Detection Technique," <i>Science</i> 241:1077-80 (1988)		
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	54	Jou et al., "Deletion Detection in the Dystrophin Gene by Multiplex Gap Ligase Chain Reaction and Immunochromatographic Strip Technology," <i>Human Mutation</i> 5:86-93 (1995)		
	55	Gibbs et al., "Detection of Single DNA Base Differences by Competitive Oligonucleotide Priming," <i>Nucleic Acids Res.</i> 17:2437-48 (1989)		
	56	Chehab et al., "Detection of Specific DNA Sequences by Fluorescence Amplification: A Color Complementation Assay," <i>Proc. Natl. Acad. Sci. USA</i> 86:9178-82 (1989)		
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	58	Nickerson et al., "Automated DNA Diagnostics Using an ELISA-Based Oligonucleotide Ligation Assay," <i>Proc. Natl. Acad. Sci. USA</i> 87:8923-27 (1990)		

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	59	Dong et al., "Mutational Studies of Human DNA Polymerase $\alpha$ ," <i>J. Biol. Chem.</i> 268(32):24175-24182 (1993)		
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	62	Eggerding, F., "A One-Step Coupled Amplification and Oligonucleotide Ligation Procedure for Multiplex Genetic Typing," <i>PCR Methods and Applications</i> 4:337-345 (1995)		
	63	Friedhoff et al., "Quantitative Polymerase Chain Reaction with Oligodeoxynucleotide Ligation Assay/Enzyme-Linked Immunosorbent Assay Detection," <i>Anal. Biochem.</i> 215:9-16 (1993)		
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	66	Jónsson et al., "Sequence of the DNA Ligase-Encoding Gene from <i>Thermus scotoductus</i> and Conserved Motifs in DNA Ligases," <i>Gene</i> 151:177-180 (1994)		
	67	Luo et al., "Improving the Fidelity of <i>Thermus thermophilus</i> DNA Ligase," <i>Nucleic Acids Res.</i> 24:3071-3078 (1996)		
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	69	Tong et al., "Biochemical Properties of a High Fidelity DNA Ligase from <i>Thermus</i> Species AK16D," <i>Nucleic Acids Research</i> 27:788-794 (1999)		
	70	Zirvi et al., "Ligase-Based Detection of Mononucleotide Repeat Sequences," <i>Nucleic Acids Research</i> 27(24):e40i-e40viii (1999)		
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	72	Takahashi et al., "Purification of HB8 DNA Ligase by Red Sepharose Chromatography," <i>Agric. Biol. Chem.</i> 50(5):1333-1334 (1986)		
	73	Takahashi, M., et al., "Thermophilic DNA Ligase Purification and Properties of the Enzyme from <i>Thermus Thermophilus</i> HB8," <i>Biol. Chem.</i> 259(16):10041-10047 (1984)		
	74	Takahashi, M., et al., "Thermophilic HB8 DNA Ligase: Effects of Polyethylene Glycols and Polyamines on Blunt-End Ligation of DNA, <i>J. Biochem.</i> , 100:123-31 (1986)		
	75	Belgrader et al., "A Multiplex PCR-Ligase Detection Reaction Assay for Human Identity Testing," <i>Genome Science &amp; Tech.</i> 1:77-87 (1996)		
	76	Newton, "The Production of PCR Products with 5' Single-Stranded Tails Using Primers That Incorporate Novel Phosphoramidite Intermediates," <i>Nucleic Acids Research</i> 21(5): 1155-1162 (1993)		

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